

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin, Bacitracin Methylene Disalicylate, and Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient monensin and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler and replacement chickens. These combination medicated feeds are used as an aid in the prevention of coccidiosis, as an aid in the prevention and control of necrotic enteritis, and for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective [insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-140 that provides for use of COBAN® (45 or 60 grams per pound (g/lb) of monensin activity as monensin sodium) and BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds containing 90 to 110 grams per ton (g/ton) monensin and 4 to 50, 50, or 100 to 200 g/ton bacitracin methylene disalicylate for use in broiler chickens and replacement chickens

intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 4 to 50 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency in replacement chickens intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 50 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler chickens and replacement chickens intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 100 to 200 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler chickens and replacement chickens intended for use as caged layers. The NADA is approved as of January 2, 2001, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraphs (f)(1)(xxix) and (f)(1)(xxx), by redesignating paragraphs (f)(4)(ii), (f)(4)(iii), and (f)(4)(iv) as paragraphs (f)(4)(iv), (f)(4)(vi), and (f)(4)(vii), and by adding paragraphs (f)(4)(ii), (f)(4)(iii), and (f)(4)(v) to read as follows:

§ 558.355 Monensin.

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(f) * * *

(1) * * *

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(xxx) *Amount per ton*. Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to bacitracin.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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(4) * * *

(ii) *Amount per ton*. Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

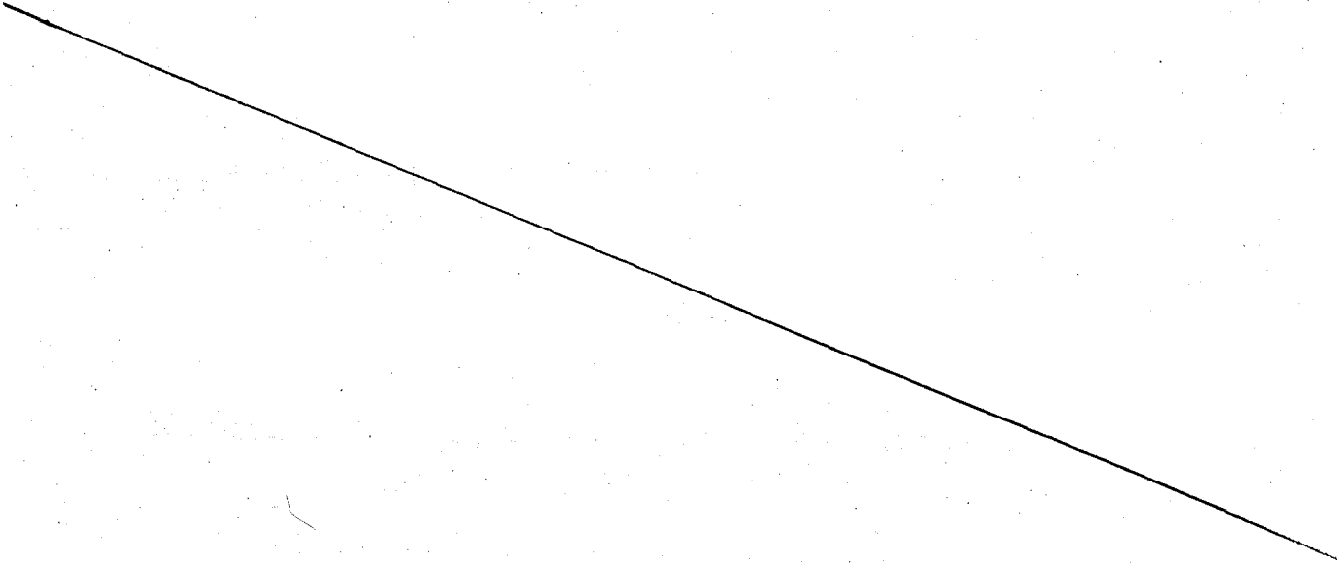
(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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(v) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5



to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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Dated: 2/12/01
February 12, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Ramona Oliver

S F Sundlof

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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